



P.B. 5918 - Patentlaan 2  
2280 HV Rijswijk (ZH)  
T (070) 340 2040  
Tx 31681 epo nl  
FAX (070) 340 9016

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D3

Denison, Christopher Marcus  
Mewburn Ellis LLP

York House

23 Kingsway [DUE]

London WC2B 6EP

GRANDE BRETAGNE

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Anmeldung Nr./Application No./Demande n° //Patent Nr./Patent No./Brevet n°

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Anmelder/Applicant/Demandeur//Patentinhaber/Proprietor/Titulaire

Virologic, Inc.

## COMMUNICATION

The European Patent Office herewith transmits the partial European search report under Rule 46(1) EPC relating to the above-mentioned European patent application.

Copies of the documents cited in the search report are enclosed.

The applicant's attention is drawn to the following:

The search Division informs the applicant that if the European search report is also to cover inventions other than the invention first mentioned in the claims, a further search fee must be paid for each of these inventions, within ONE MONTH after notification of this communication.

If the application has been filed up to 30 June 1999, the search fee in force before 01 July 1999 (EUR 869,-) or the equivalent applicable on the date of payment is payable.  
This applies also to the search fees requested under Rule 46(1) EPC.  
See also OJ EPO 06/1999, 405.

The abstract was modified by the Search Division and the definitive text is attached to the present communication.

Additional set(s) of copies of the documents cited in the European search report is (are) enclosed as well.



### Note to users of the automatic debiting procedure:

Unless the EPO receives prior instructions to the contrary, the search fee(s) will be debited on the last day of the period for payment. For further details see the Arrangements for the automatic debiting procedure, Supplement to OJ EPO 02/1999.

REGISTERED LETTER



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**SUPPLEMENTARY  
PARTIAL EUROPEAN SEARCH REPORT**  
under Rule 46, paragraph 1 of the European Patent Convention

Application Number  
EP 01 94 4452

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	WO 99/61658 A (VIROLOGIC INC) 2 December 1999 (1999-12-02) * claims 1-72 *	1-6	C12Q1/70
Y	WO 97/27332 A (INNOGENETICS NV ; STUYVER LIEVEN (BE); LOUWAGIE JOOST (BE); ROSSAU RUD) 31 July 1997 (1997-07-31) * page 4, line 15 ~ page 5, line 11; table 2 *	1-6	
Y	CLERCQ DE E: "DEVELOPMENT OF RESISTANCE OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) TO ANTI-HIV AGENTS: HOW TO PREVENT THE PROBLEM?" INTERNATIONAL JOURNAL OF ANTIMICROBIAL AGENTS, AMSTERDAM, NL, Vol. 9, no. 1, 1997, pages 21-36, XP000878561 ISSN: 0924-8579 * the whole document *	1-6	
		-/-	TECHNICAL FIELDS SEARCHED (Int.Cl.7)  C12Q
<b>LACK OF UNITY OF INVENTION</b>			
The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:			
see sheet B			
The present partial European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims.			
4 EP0 FORM 1503 01 02 (P0013)	Place of search	Date of completion of the search	Examiner
	The Hague	27 October 2004	Schmitt, A
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background D : non-written disclosure P : intermediate document			



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## PARTIAL EUROPEAN SEARCH REPORT

Application Number  
EP 01 94 4452

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
Y	<p>SALOMON H ET AL: "Prevalence of HIV-1 resistant to antiretroviral drugs in 81 individuals newly infected by sexual contact or injecting drug use. Investigators of the Quebec Primary Infection Study." AIDS (LONDON, ENGLAND) 28 JAN 2000, vol. 14, no. 2, 28 January 2000 (2000-01-28), pages F17-F23, XP008037438 ISSN: 0269-9370 * the whole document *</p> <p>-----</p>	1-6	
Y	<p>MELLORS J W ET AL: "MUTATIONS IN HIV-1 REVERSE TRANSCRIPTASE AND PROTEASE ASSOCIATED WITH DRUG RESISTANCE" INTERNATIONAL ANTIVIRAL NEWS, CHURCHILL LIVINGSTONE, EDINBURGH, GB, vol. 3, 1995, pages 8-13, XP000614717 ISSN: 0965-2310 * the whole document *</p> <p>-----</p>	1-6	TECHNICAL FIELDS SEARCHED (Int.Cl.7)
A	<p>KANKI P J ET AL: "VIROLOGY OF HIV-1 AND HIV-2: IMPLICATIONS FOR AFRICA" AIDS, LONDON, GB, vol. 11, no. SUPPL B, 1997, pages S33-S42, XP008035289 ISSN: 0269-9370 * the whole document *</p> <p>-----</p>	1-6	
4			



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-6 (partially)

Method for assessing the effectiveness of non-nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient's plasma sample contains nucleic acid encoding HIV reverse transcriptase (HIV-RT) having a mutation at codon 230 or at codons 230 and 103, or at codons 230 and 181; and method and resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codon(s).

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2. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230 and 101.

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3. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230 and 190.

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4. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230 and 221.

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5. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230 and 238.

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6. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 103.

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7. claims: 1-6 (partially)



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 190.

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8. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 221.

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9. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 238.

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10. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 103, 190.

---

11. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 103, 221.

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12. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 103, 238.

---

13. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 190, 221.

---

14. claims: 1-6 (partially)



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 190, 238.

15. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 221, 238.

16. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 103, 190.

17. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 103, 221.

18. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 103, 238.

19. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 190, 221.

20. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 190, 238.

21. claims: 1-6 (partially)



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 221, 238.

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22. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 103, 190, 221.

---

23. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 103, 190, 238.

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24. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 103, 221, 238.

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25. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 190, 221, 238.

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26. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 103, 190, 221.

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27. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 103, 190, 238.

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28. claims: 1-6 (partially)



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 103, 221, 238.

29. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 190, 221, 238.

30. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 103, 190, 221, 238.

31. claims: 1-6 (partially)

Methods and resistance test vector as described in the previous invention, wherein the HIV-RT has mutations at codons 230, 101, 103, 190, 221, 238.

32. claims: 1-6 (partially)

Method for assessing the effectiveness of non-nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient's plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 241 or at codon 241 and further codons; and method and resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at codon 241 or at codon 241 and further codons.

33. claims: 1-6 (partially)



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

Method for assessing the effectiveness of non-nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient's plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 245 or at codon 245 and further codons; and method and resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment 'of reverse transcriptase! which comprises a mutation at codon 245 or at codon 245 and further codons.

34. claims: 1-6 (partially)

Method for assessing the effectiveness of non-nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient's plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 270 or at codon 270 and further codons; and method and resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment 'of reverse transcriptase! which comprises a mutation at codon 270 or at codon 270 and further codons.

The Applicant is to note that if the Applicant pays additional fees for one (or more) not yet searched group(s) of invention(s) as defined above, then the further search(es) may reveal further prior art that gives evidence of a further lack of unity 'a posteriori' within one (or more) of the not yet searched group(s).

**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

**EP 01 94 4452**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

**27-10-2004**

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
WO 9961658	A	02-12-1999	AU	772511 B2		29-04-2004
			AU	4207599 A		13-12-1999
			BR	9911600 A		13-02-2001
			CA	2329140 A1		02-12-1999
			CN	1311823 T		05-09-2001
			EP	1082454 A1		14-03-2001
			JP	2002516119 T		04-06-2002
			MX	PA00011623 A		17-10-2002
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			AU	1444397 A		20-08-1997
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			JP	11502727 T		09-03-1999
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			US	6087093 A		11-07-2000
			US	2003077575 A1		24-04-2003

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